

Standards Navigator

Standards Navigator Monthly Report

1-February-2012

SoftwareCPR Standards Navigator provides information and tools related to standards that play a significant role in health software and software intensive medical devices. In addition to information on existing standards, SoftwareCPR Standards Navigator keeps you up to date on new standards activity and gives you expert insight into future changes to existing standards.

<http://www.softwarecpr.com/topicsframepage.htm>

Standards Activity Status – January 2012

HEALTH SECTOR SOFTWARE STANDARDS

NEW	<p>The EU Medical Device Experts Group has approved guidelines for the boundaries of what software products are considered medical devices in the EU. This document has just been published as MEDDEV 2.1/6.</p> <p><i>The MEDDEV document can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO TR 17791 NEW (in IEC)	<p>Guidance on Standards for Enabling Safety in Health Software</p> <p>ISO/TC 215 has agreed that this work should be done as a joint project with IEC/TC 62. A new work item has been circulated in IEC and, if approved, will be assigned to JWG7 with an ISO project lead. The new work item has already been approved in ISO/TC 215. The intent of this work item is to identify and assemble a globally-accepted “package” of standards that will provide guidance to countries, health software developers, implementers and end users to ensure that health software appropriately protects the safety of patients.</p> <p><i>The NWIP can be found on the SoftwareCPR Standards Navigator web page.</i></p>
Institute of Medicine report – Health IT and patient safety NEW	<p>The Institute of Medicine produced a report on the impact of Health IT on patient safety. The report had a number of recommendations for the Secretary of HHS.</p> <p><i>A presentation on the recommendations and the entire report are available at the SoftwareCPR Standards Navigator web page.</i></p>
NEW	<p>The FDA has invited numerous standards developing organizations and a few other stakeholders to meet for the purpose of coordinating standards activities related to medical device interoperability. The first teleconference was held on January 23. A face-to-face meeting is planned for March 9.</p>

MEDICAL DEVICE STANDARDS

JIS T2304 NEW	Japan has adopted IEC 62304 as a JIS. Legislation is expected to be introduced this year to change the PAL to include standalone software as a medical device in Japan.
IEC 60601-1-6 NEW	<p><i>Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability – Amendment 1</i></p> <p>A Committee Draft for the first amendment of IEC 60601-1-6 has been circulated. The third edition of IEC 60601-1-6 was published in 2010. The third edition created a bridge that enables a MANUFACTURER to conform to the requirements in IEC 60601-1 that make normative reference to IEC 60601-1-6 by employing a USABILITY ENGINEERING PROCESS complying with IEC 62366:2007. However, IEC 62366 contains certain life-cycle process elements that are inconsistent with a type examination. This amendment is intended to clarify the elements of the USABILITY ENGINEERING PROCESS that are required for compliance with IEC 60601-1 series.</p> <p><i>The CD can be found on the SoftwareCPR Standards Navigator web page.</i></p>
IEC 60601-1-12 NEW	<p><i>IEC 60601-1-12 Ed. 1.0 : Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment</i></p> <p>A Committee draft for vote (CDV) for this new standard has been circulated. The ballot will close on June 15, 2012.</p> <p><i>The CDV can be found on the SoftwareCPR Standards Navigator web page.</i></p>
ISO 13485	<p>Medical devices – Quality management systems – Requirements for regulatory purposes</p> <p>ISO has approved a revision of ISO 13485. As part of the ISO requirements for new or modified management system standards, a justification for the revision must be produced. A justification has been developed and is currently being voted on.</p> <p><i>The justification document can be found on the SoftwareCPR Standards Navigator web page.</i></p>
NWIP	<p>Medical devices - Selection and use of standards in support of recognized essential principles of safety and performance of medical devices</p> <p>This Standard identifies significant standards and guides that can be used in the assessment of conformity of medical devices with recognized essential principles of safety and performance. It also provides guidance in the use of standards and their application in conformity assessment.</p> <p>This proposed third edition of ISO Technical Report 16142 will be developed as an international standard and is intended to identify additional links between existing international standards and the revised and updated Global Harmonization Task Force Essential Principles.</p> <p><i>The NWIP can be found on the SoftwareCPR Standards Navigator web page.</i></p>

MEDICAL IT NETWORKS

IEC TR 80001-2-1	<p>Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by step risk management of medical IT-networks; Practical applications and examples</p> <p>This TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012.</p>
IEC TR 80001-2-2	<p>Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls</p> <p>This TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012.</p>
IEC TR 80001-2-3	<p>Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks</p> <p>This TR was approved in IEC. It has been circulated in ISO with the ballot closing on February 4, 2012.</p>

GENERAL SOFTWARE STANDARDS

<p>NWIP - Capabilities of software testing tools</p> <p>ISO/IEC JTC1/SC7 NEW</p>	<p>The scope of this work is to define the capabilities of tools that make it possible to fully or partially automate the software testing.</p> <p><i>The draft NWIP can be found on the SoftwareCPR Standards Navigator web page until April 28, 2012.</i></p>
ISO/IEC 29119-2	<p>Software Testing — Part 2: Test Process</p> <p>This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012.</p> <p><i>The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.</i></p>
ISO/IEC 29119-3	<p>Software Testing — Part 3: Test Documentation</p> <p>This DIS has been circulated in JTC1 with the ballot closing on May 9, 2012.</p> <p><i>The draft can be found on the SoftwareCPR Standards Navigator web page until May 8, 2012.</i></p>

ISO/IEC 20000-3	<p>Information technology – Service management – Part 3: Guidance on scope definition and applicability of ISO/IEC 20000-1</p> <p>This DIS has been circulated in JTC1 with the ballot closing on May 3, 2012.</p> <p><i>The draft can be found on the SoftwareCPR Standards Navigator web page until May 2, 2012.</i></p>
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